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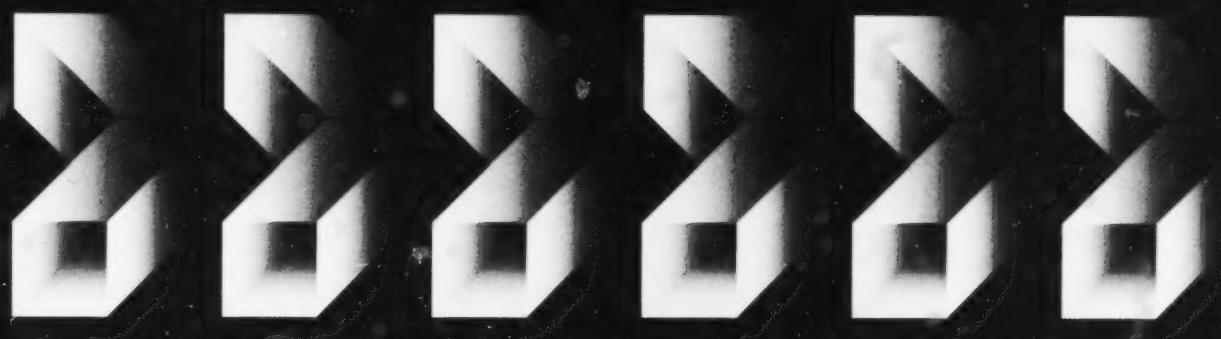

THERATRONICS CASE STUDY: TECHNICAL REPORT #1

EVALUATION OF THE ENVIRONMENTAL HAZARDS PROGRAM

August 1995

Canada

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THE BUREAU OF RADIATION AND MEDICAL DEVICES RESPONSE TO PROBLEMS WITH THERATRONICS PRODUCTS: A CASE STUDY

by

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The analysis, conclusions and recommendations found in this consultants' report are those of its authors and are not necessarily shared by the Department of National Health and Welfare.

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1. INTRODUCTION

The purpose of this report is to address several questions, on behalf of the Program Evaluation Division of Health Canada, about the performance of the Environmental Health Directorate concerning the investigation of problems with Theratronics cobalt 60 radiotherapy equipment and treatment planning systems. These questions, which are presented in Appendix I, pertain to the actions taken with regard to the problems, the effectiveness of communication with other government bodies and with the general public, and the use made of the Health Protection Branch's risk assessment and risk management model.

For the purposes of this report, we have considered that the evaluation period ended on 31 March 1994.[1] The main content of the report is based on documentation received at the start of the project (May 1994), information gathered during interviews conducted during June to August 1994, and additional documentation provided to us in the interview period. We have incorporated review comments on the draft version of the report (which was written in October 1994). Where these comments substantially differed from our original information, we have identified their origin in this final report.

1.1. THE X-RAY SECTION

It appears from the evaluation description, the documents provided to us at the start of the project, and subsequent discussions during the project, that the responsibility for the Environmental Health Directorate's response to problems arising from Theratronics products lay mainly with the X-ray Section of the then Bureau of Radiation and Medical Devices (BRMD).[2] According to the Environmental Health Directorate's *Project Area Reviews (Number 03: X-rays)* [Symonds (1993a, 1994)], this Section is primarily concerned with "activities related to the assessment and management of risks

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1 The end of the fiscal year in which the Request for Proposal (RFP) for the project was sent out.

2 As a result of the recent reorganization within the Directorate, the X-ray Section is now part of the Radiation Protection Bureau (RPB). The report will use the former Bureau designation — namely, the Bureau of Radiation and Medical Devices (BRMD) — as it was relevant at the time of the Theratronics investigations. On occasion, however, our account makes reference to current situation — in these instances we shall use the current Bureau's designation, namely RPB. All representatives of Health Canada interviewed as part of this case study are officers of the RPB.

associated with the use of medical and industrial x-ray and electron beam devices". The Directorate's action with regard to Theratronics presumably fell under the secondary objective of this Project Area, namely:[3]

> "to provide technical and scientific support to the radiation protection and other Directorate programmes by;
>
> > developing expertise in radiation, electrical, mechanical and software safety of specific classes of new radiation emitting devices and other devices,
> >
> > providing engineering support in the fields of computer-controlled systems and electronics,
> >
> > serving as a resource centre for the harmonization of technical requirements between regulatory and other Canadian and international standards."

We could not help noticing, however, that in neither the 1993 nor the 1994 *Project Area Reviews* was investigation of Theratronics products identified as a goal. The only reference in the Reviews to the investigation appears in explanations as to why certain project-area goals had not been completed on time and why certain project-area initiatives had been delayed. It seems clear, therefore, that investigation of problems with Theratronics products was not an activity for which allowance had been made in project planning over the last two or three years.[4]

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[3] This is the description provided in the latest *Project Area Reviews* [Symonds (1994)]. A slightly different description appears in last year's *Reviews* [Symonds (1993a)]:

"to provide technical and scientific support to the medical devices programme by;
developing expertise in radiation, electrical, mechanical and software safety of specific classes of new medical devices,
providing engineering support in the fields of computer-controlled systems and electronics,
serving as a resource centre for the harmonization of technical requirements between regulatory and other Canadian and international standards."

[4] A reviewer of the draft version of this report provided the following explanation:

"This activity was not explicitly allocated any time at Project Area Review, but was included in 033804 '[T]o provide advisory and technical support and assistance ...'. Cases like this may arise from outside the country (for example, the USFDA), and in any event cannot be foreseen or planned for — they just happen and we must act on them."

1.2. APPROACH ADOPTED

In conducting this case study, we obtained information from two main sources — structured interviews with federal-government employees associated with the program[5] and a review of pertinent documentation. Our review of documents for this case study was limited to material supplied by the Program Evaluation Division at the beginning of the study, and documents identified or provided as a result of the interviews. We did not undertake an independent literature search. The documents that formed part of this review are listed in Appendix II

After familiarizing ourselves with the general aspects of the case study through a preliminary perusal of the supplied documentation, a series of interviews was conducted. The initial step involved a short meeting with the contact person identified by the Program Evaluation Division for this case study.[6] During this meeting we briefly outlined the purpose of the case study and asked for names of individuals who would be able to help in answering the evaluation questions (presented in Appendix I). Three people, including the contact person, were identified and face-to-face interviews were carried out. In the course of the interviews, it became apparent that the Atomic Energy Control Board (AECB) was also concerned with aspects of the licensing and use of radiotherapy equipment. Accordingly we also interviewed two representatives from that Agency.

Two team members were used in each face-to-face interview and, prior to each interview, interviewees were sent outlines of the topics we wished to discuss. After each interview, a point-form account of the session was prepared and sent to the interviewee for comment. Comments from the interviewees were incorporated in the interview accounts and these accounts then formed one of the bases from which we answered the project's evaluation questions. The topics discussed during the interviews fell into four categories:

(1) the organizational "structure" and "history" of the components within the Health Protection Branch (HPB) that deal with radiotherapy equipment,

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5 It was not part of our mandate to contact individuals outside the federal government.

6 Mr. Gordon Symonds, Head, Advanced Systems Unit, X-ray Section, Radiation Protection Bureau.

(2) statutory and regulatory aspects of the case study,

(3) the use of HPB's risk assessment/risk management model,

and, because it formed a major part of the evaluation questions we had been asked to address,

(4) communications.

These are summarised in Table 1-1. The responses to the interviews are summarised in Appendix III.

1.3 QUALITY ASSURANCE STANDARDS

The HPB risk assessment/risk management model carefully considers the costs of risk management and recommends that "the efficiency of each option in reducing or preventing risk should be considered, along with the resources required to implement it" [HPB (1990), p.45]. One option that is receiving increasing attention is to require manufacturers of equipment to work to internationally accepted quality assurance standards. This approach has the potential, in the longer term, to reduce surveillance costs and efforts, to reduce wastage in manufacture, and to result in higher quality products in service.

The concept of quality assurance is one that is subject to widespread misunderstanding. A product that has been developed and produced to a quality assurance program does not necessarily have high performance specifications, nor a quality appearance, nor even superior reliability characteristics. What can be depended upon, however, is that "All those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality" [ISO (1987a)] have been implemented. Further, quality assurance is not complete unless the given requirements fully reflect the needs of the user and, to be effective, quality assurance requires a continuing evaluation of factors that affect the adequacy of the design or specification to the intended application, as well as verifications and audits of production, installation, and inspections.

TABLE 1-1 *Topics Discussed During the Interviews**

ORGANIZATIONAL STRUCTURE AND HISTORY
• THE BUREAU OF RADIATION AND MEDICAL DEVICES
• THE FIELD OPERATIONS DIRECTORATE
• EXTERNAL AGENCIES (AECB, USFDA, AND OTHERS)
STATUTORY CONSIDERATIONS
• GENERAL STATUTORY INSTRUMENTS
• THE SITUATION WITH REGARD TO PATIENT SAFETY
• RESPONDENTS THOUGHTS ON REGULATORY APPROACHES
RISK ASSESSMENT/RISK MANAGEMENT
• THE "PHILOSOPHY"
• THE PRACTICE
COMMUNICATIONS
• THE HEALTH CANADA APPROACH
• THE ATOMIC ENERGY CONTROL BOARD APPROACH.

* A summary of the responses is presented in Appendix III.

Quality assurance should not be confused with quality control, although the latter is one essential aspect of quality assurance. Quality control is often referred to as "inspection" during the production process, but it also includes metrology (standardized tools to do the job), inspection of incoming goods against specifications, storekeeping and records, and may include measurements against performance specifications. Quality control is also required during design and development, installation, and field service, although requirements vary for each stage. Quality assurance includes a commitment by top management to a quality policy, and to have an organizational structure in place to develop more detailed policy objectives, with defined responsibilities, procedures, processes, and adequate resources for its implementation.

Formal quality assurance systems were first developed in critical high-risk industries; to meet military requirements, for the USA space program, and for the nuclear reactor industry. In Canada, the requirements of the power reactor program were largely responsible for the development of the CSA Z299 series of standards [CSA (1986)], with Z299.1 being the strictest standard; mandatory for the supply of critical reactor components. The regulators of the radiation therapy industry have been slower to adopt similar standards, but have recently moved in this direction, including the development of international standards. The development of quality assurance systems for software has been somewhat slower, for at least three reasons:

i) historically, software specialists have tended to treat their art as a creative activity, resisting attempts to formalize their work;

ii) except for very simple systems, the extremely large number of possible combinations of possible paths in software render it impractical to provide 100 percent certainty that a computer program contains no faults; and

iii) the cost of a formalized structure for software development and testing is considerable, and must be measured against advantages that cannot be quantified in advance.

For these reasons, there have been two basic approaches to the development of commercial software: (1) that used by the military/aerospace industry, where cost is only a minimal consideration; and (2) everybody else, with manufacturers of medical devices, for the most part, being in the second group [Symonds (1993b)].

Certain international quality assurance standards are currently being considered by regulators of teletherapy and other medical equipment. These include the ISO 9000 series [ISO, (1987a,b,c,d,e)] and IEC 601-1 [IEC (1990)]. All these standards are designed for use with hardware. International standards for software are still in the draft stage of development, with both ISO and the IEC having standards in progress. The BRMD are active participants in these activities.

Resulting from the 1992 audit of Theratronics (described in Section 2.4), both the United States' Food and Drug Administration (USFDA) and the Health Protection Branch's Field Operations Directorate (FOD) required the manufacturer to implement or improve several aspects of their quality assurance programmes before they would lift the recall and stop-shipment orders issued, respectively, by the USFDA and the FOD.

2. BACKGROUND

Before discussing our findings (which will be presented in the next chapter), it is necessary to provide some background to the situation that resulted in the Bureau of Radiation and Medical Devices being called upon to investigate problems with Theratronics cobalt 60 radiotherapy equipment and treatment planning systems. In doing so, we shall first briefly examine, in a general and non-legal manner, the statutes and regulations that appear to have a bearing on the project.[7] The structure within the Health Protection Branch was pertinent to the situation that led to the investigation and a brief overview is therefore presented next. Atomic Energy of Canada (AECL)/Theratronics was (and is) a pioneer in the development of radiotherapy equipment and is the only Canadian manufacturer of such equipment and we provide a brief description of the company's role in radiation therapy to give context to the discussions in our report. Finally, we conclude the chapter with an examination of the situation that led to the investigations being carried out.

2.1 STATUTORY CONSIDERATIONS

In addition to Health Canada's general duties under the *National Health and Welfare Act*, there are at least two statutes that have a bearing on radiotherapy equipment and treatment planning systems — the *Food and Drugs Act* [8] and the *Radiation Emitting Devices Act*.[9] Both these Acts are the direct responsibility of the Minister of National Health and Welfare.

The *Food and Drugs Act* is a very broad piece of legislation and it is the sections (s. 19, s. 20, and s. 21) dealing with "devices" and the attendant Medical Devices Regulations[10] that are pertinent. Under the Act, a "device" is described (in part) as:

---

7 We stress that this (and any subsequent commentary on statutory and regulatory aspects in later stages of our report) is a discussion from a "lay" point of view. We possess neither the specific expertise nor the professional qualifications to offer legal opinions.

8 R.S.C. 1985, c. F-27, as amended.

9 R.S.C 1985, c. 34(1st Supp.).

10 C.R.C. 1978, c. 871, as amended.

> ... any article, instruments, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in
>
> (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or the symptoms thereof, in man or animal.

And this is a definition that clearly includes cobalt 60 teletherapy equipment. What is less clear, we gather from our interview discussions and from documents provided to us (see, for example, Symonds [1992a]), is whether treatment planning systems fall within the definition of "devices" under the Act. These are computer-based systems that utilize several sources of information,[11] perform complex calculations, and allow the radiotherapist to visualize the dose distributions in the patient. They are generally applicable to radiation therapy and are not specific to a particular teletherapy machine.

The *Radiation Emitting Devices Act*, "an Act respecting the sale and importation of certain radiation emitting devices", defines a radiation emitting device as (s.2):

> (a) any device that is capable of producing and emitting radiation; and

---

[11] These information sources include:

- beam data from teletherapy equipment manufacturers, both cobalt 60 and accelerators, in analog or digital form;
- similar data, developed by the treatment centre, or provided by recognized authorities (British Journal of Radiology tables [BJR (1983)], for example);
- tables, extracted and massaged from the above, to facilitate the calculation process (Cunningham, a pioneer in the development of treatment planning system techniques, breaks the radiation into "primary" and "secondary", and uses "tumour-air-ratios" and "scatter-air-ratios" for calculation purposes);
- information about the shape and size of the patient. This used to be provided by flexible lead wires within plastic or rubber (French curves), laboriously transferred from the patient to a drafting board. This information can now be provided more easily and accurately by CT scanners (provided scale factors are all correct). Corrections must/should also be made for oblique entry angles of the beam;
- estimates of the sizes and densities of certain body parts. Most of the body can be considered as water (similar atomic composition and density), but corrections need to be made for the lower density of the lungs, for certain body orifices, and for the higher density of bone, which also has a significantly different chemical composition. Diagnostic X-ray machines and CT scanners provide this information;
- estimates of the size and shape of the tumour(s). The older methods often guessed at this, by dislocation of body organs, as shown on X-rays, and by external examination (I feel a lump here). CT scanners and especially, MR devices, have taken much of the guess work away; and
- calculations, derived from a knowledge of radioisotopes entered in the body, by brachytherapy or implants.

(b) any component of or accessory to a device described in paragraph (a).

and radiation as:

... energy in the form of electromagnetic waves or acoustical waves.

Given that the γ–radiation emitted by cobalt 60 therapy machines is a form of electromagnetic radiation (which, under quantum theory, can be mathematically described in terms of wave motion), such machines would, at first sight, appear to be covered under the Act. But we were told that cobalt 60 therapy machines were excluded by s. 3 of the Act. The section states:

3. This Act does not apply to

(a) a radiation emitting device that is designed primarily for the production of atomic energy within the meaning of the *Atomic Energy Control Act*.

In s. 2 of the *Atomic Energy Control Act*[12] , "atomic energy" is defined as:

... all energy of whatever type derived from or created by the transmutation of atoms.

And the γ–radiation emitted by cobalt 60 therapy machines is generated in the process of transmutation of radioactive cobalt 60 to non-radioactive nickel 60.

The *Atomic Energy Control Act* (which was originally introduced to protect national security) is administered by the Atomic Energy Control Board (AECB). This Agency is involved in the licensing and use of atomic energy and of "prescribed substances" as described under the Act:

... "prescribed substances" means uranium, thorium, plutonium, neptunium, deuterium, their respective derivatives and compounds and such other substances as the Board may by regulation designate as being capable of releasing atomic energy or as being requisite for the production, use or application of atomic energy.

Cobalt 60 is one radioactive element (among many) that is identified in the Atomic Energy Control Regulations[13] as being a prescribed substance.

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12 R.S.C 1985, c. A-19.

13 C.R.C. 1978, c. 365, as amended.

The AECB acknowledges responsibility for cobalt 60 teletherapy facilities — see for example, *A Guide for Approval of Cobalt Teletherapy Installations* [AECB (1990)] — and also for the operators of such facilities.[14] It also is concerned with the safety of the general public by setting limits, based on Schedule II of the Atomic Energy Control Regulations, on the maximum allowable radiation that may be present at the "perimeter" of such installations. The AECB, however, claims that it has no jurisdiction regarding safety of patients[15] undergoing radiation therapy; citing as evidence the exclusion clause to the Schedule II table of maximum permissible doses which states (in part):

> (1) The maximum permissible doses and exposures specified in this Table do not apply to ionizing radiation
>
> (a) received by a patient in the course of medical diagnosis or treatment by a qualified medical practitioner.

This exclusion, of course, makes perfect sense because radiation doses used in radiation therapy are several orders of magnitude higher than those experienced by the general public from background radiation.[16] Presumably, in this case, it is accepted that the prime responsibility for the patient lies with the treating physician.[17]

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14 Operators of such equipment are, of course, also covered by provincial occupational health and safety legislation.

15 A rider to this comment was provided by a reviewer of the draft version of this report who stated that the AECB "is considering a statutory role in patient safety". However, at the time we conducted interviews with AECB personnel, we were specifically told that Board "did not consider it has responsibility for patient safety" and, furthermore, we were told that "[T]here are no specific regulations in Canada governing the safety of patients undergoing radiation therapy — patient safety is covered in a general way by parts of the *Radiation Emitting Devices Act* and the Medical Devices Regulations of the *Food and Drugs Act*" (see Appendix III of this report).

16 The dose to the tumour, in Ontario treatment centres (for example) is 1000 rem per week, which is five orders of magnitude greater than the maximum allowed to the general public (10 mrem per week, averaged annually). The whole-body dose to the patient is at least two orders of magnitude greater than that experienced by the general public.

17 These medical practitioners are licensed to practice by the provinces in which they work. They, in turn, rely on the services of medical physicists and medical radiation technologists (individuals who are also licensed by the provinces) to develop appropriate treatment regimes.

There are clearly areas of overlapping (and, perhaps, even competing) jurisdiction with regard to cobalt 60 teletherapy equipment[18] between Health Canada and the AECB.[19] Because of this, we asked if there were any Memoranda of Understanding between these two agencies that would help clarify matters. The only document that we were provided with, entitled "Memorandum of Understanding Between the Atomic Energy Control Board and the Department of National Health and Welfare" [Fry and Jennekens (1981)], was very general in nature and did not deal with cobalt 60 radiation therapy. It dealt with such items as public- and occupational-health matters stemming from radiation, standards and regulation development, personnel radiation dosimetry services, and licensing matters regarding the clinical uses of medical radioisotopes. The only reference to radiation therapy involved agreement between the two parties "to continue to consult with each other with respect to the licensing of particle accelerators".

Although not Canadian legislation, the powers of the United States' Food and Drugs Administration (USFDA) are very pertinent to this case study. The USFDA operates with the authority of the detailed and demanding Regulations of 21 CFR Chapter 1. Subchapter J: Radiological Health [USFDA (1991)], which defines requirements for record keeping and reporting in considerable detail. This is further defined in Part 803 — Medical Device Reporting [USFDA (1991)], which details the conditions that must be reported and in what manner. The intent of these U.S. Regulations is both proactive and confrontational, and it is in this manner that they tend to be followed by the USFDA. For example, if there is an incident resulting in or which could have resulted in death or serious injury *from whatever cause, anywhere in the world* , by equipment that is also sold in the USA, that manufacturer is required to submit *detailed reports* to the USFDA *to a rigid time schedule*. The USFDA may, without cause, enter the premises of any Company offering equipment to be used in the USA, and demand an inspection of their records.

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18 AECB stated that they have no jurisdictional interest concerning treatment-planning systems.

19 An alternative interpretation was provided by a reviewer of the draft version of this report who stated:

"It has never been the case that overlapping areas of jurisdiction existed between AECB and NHW with regard to cobalt teletherapy equipment. AECB has jurisdiction over the source and is responsible for radiation safety, while Health Canada's jurisdiction includes the regulation of therapy machines as medical devices."

2.2 STRUCTURE WITHIN THE HEALTH PROTECTION BRANCH

For most of the period covered by the program evaluation,[20] the Bureau of Radiation and Medical Devices (BRMD) within the Environmental Health Directorate dealt with cobalt 60 teletherapy and with treatment planning systems. Another Directorate in the Health Protection Branch, the Field Operations Directorate, was also actively involved.

The Bureau of Radiation and Medical Devices was formed in 1986 by the amalgamation of two Bureaus — the Radiation Protection Bureau (RPB) and the Bureau of Medical Devices (BMD). Prior to this date, the BMD dealt strictly with matters covered by the Medical Devices Regulations of the *Food and Drugs Act* — the RPB, under a Memorandum of Understanding, acted as advisor to, and on behalf of, BMD in matters involving radiation. The RPB carried out the inspectorate functions under the *Radiation Emitting Devices Act* and this component continued to do so in the amalgamated Bureau. In September 1993, BRMD was again split into the two component Bureaus.

The Field Operations Directorate was responsible for "identifying, assessing, and managing health and safety risks associated with the manufacture and sale of (among many items) radiation emitting devices" [HPB (1990)]. This Directorate carried out the inspectorate functions of the *Food and Drugs Act.* The BRMD was asked by this Directorate for advice on matters involving radiation but, as we detail in the next chapter, sometimes not before action had already been taken. As of 15 July 1994, the Field Operations Directorate no longer exists as such and its inspectorate functions regarding medical and radiation emitting devices will be under the functional direction of the Director General, Environmental Health Directorate.

2.3 ATOMIC ENERGY OF CANADA LIMITED/THERATRONICS

Although a purpose of this study is to evaluate the advice given and actions taken by the BRMD with respect to Theratronics (formerly part of Atomic Energy of Canada

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20 Ostensibly the period from the date of the previous program evaluation (August 1984) to the end of the 1993/94 fiscal year.

Limited, Commercial Products), rather than to make an evaluation of the actions of Theratronics themselves, we feel that a capsule history of that Company may serve to bring the actions of the BRMD and other regulatory agencies into perspective.

Atomic Energy of Canada Ltd.: Commercial Products (AECL-CP) was formed in 1953 by an amalgamation of two groups; one a team from Eldorado Mining and Refining (Eldorado) at Port Hope, and the other a group within the AECL development laboratories at Chalk River [Bothwell (1988)]. For more than thirty years AECL-CP operated within the AECL umbrella, but with considerable corporate freedom. In the mid-1980's, the government decided to privatize AECL-CP, and the organization was divided into two Companies, Nordion International Inc. and Theratronics International Ltd. Theratronics is still a Crown Agency which continues to manufacture equipment related to the treatment of cancer.

2.3.1 Cobalt 60 Teletherapy Equipment

Canada has been a leader in the field of cobalt 60 teletherapy from the outset [Bothwell (1988)]. The first commercial unit was produced by Eldorado Mining and Refining in 1951. After joining forces with AECL, they established offices in Ottawa and developed a marketing arm. By 1953 AECL-CP was designing, manufacturing, and marketing this equipment. Their technical and commercial success has been remarkable: they have installed approximately 2,000 of these machines, representing more than one-half of the world supply, in every major country on all continents of the world.

At various times there have been safety related problems with these machines. As an example, due to fatigue failure, cracks were discovered in the arms of some Theratron 60/80 cobalt teletherapy machines in the early 1970's. Fortunately AECL was able to take corrective action and prevent any accidents occurring. In 1980/81 there were two types of failures that resulted in recalls which were soon resolved [Dvorak (1981), Mahmud (1980), Gundaker (1980)]; these were referred to as the cord reel problem and the single digital timer problem. A number of other problems surfaced in 1992, and it is these problems that concern us in this study.

2.3.2 Medical Electron Accelerators

Although an examination of Theratronics' experience with accelerators is not within the mandate of this study, some aspects of this product line, and the Therac 25 in particular, have a direct bearing on how Theratronics was (and, probably, still is) viewed by regulatory bodies. Medical electron accelerators are machines that accelerate thermal electrons to a high energy, such that they may be used in the treatment of cancerous lesions or may, by impinging the electrons against a "target", produce X-rays which may be used for the same purpose. Most rotational units move about an axis 100 cm from the point of origin of the radiation beam; this is called the source to axis distance (SAD). This SAD is somewhat greater than most rotational cobalt 60 machines, although the Theratron 1000 also has an SAD of 100 cm. The electrons produced by accelerators are more readily absorbed by tissue than are cobalt 60 γ-rays, and the X-rays produced by accelerators are the most penetrating of these radiations.

About 1970, a reliable low energy (4 MeV) accelerator was introduced for treatment of cancer (the Clinac 4), which soon made inroads into AECL's cobalt 60 teletherapy market. Atomic Energy of Canada Limited responded by entering into a cooperative venture with Companie Général de Radiologie (CGR) of France, who were established in medical accelerator technology, but did not have a cobalt teletherapy machine, nor AECL-CP's marketing capabilities. They first developed the Therac 6, based on the CGR Neptune accelerator, an early design, then the Therac 20, based on CGR's then recently-introduced Saturn. From the beginning, AECL used a small computer as a control console, and for record keeping. Meanwhile, AECL's Chalk River Laboratories were developing a medical accelerator, which incorporated the unique concept of a turn-around magnet, making the machine more compact. This machine was capable of treating with electrons and either of two X-Ray energies. The role of the computer in this machine was expanded by AECL-CP, who also used it for most aspects of machine control. Unfortunately, serious deficiencies in the software/hardware interface of the Therac 25 led to machine failures that resulted in a serious injury to a patient in Canada and several fatalities in the USA [Symonds (1993b), Leveson and Turner (1993)]. Theratronics (then AECL-CP) expended large amounts of human and financial resources to correct these problems and to settle litigation. One result of this misadventure was that Theratronics withdrew from the medical accelerator business.

2.3.3 Treatment Planning Systems

Treatment planning, in the limited sense that we use the term in this study,[21] is the process by which the following are combined:

1. the radiation characteristics of one or more modalities of one or more sources of radiation, and their orientations with respect to the tumour(s),
2. the physical shape, size, density, and chemical composition of the patient in the region of the body being treated, and
3. a knowledge of the physics of the interaction of radiation with matter.

to devise the best practical approach to the treatment of a patient by radiology.

Treatment planning has always been a vital component of radiation therapy. Initially treatment plans were developed using laborious hand calculations. With the advent of digital computers, researchers modified their mathematical models and developed more sophisticated and accurate methods of estimating the radiation dose distributions. A paramount leader in this field was Dr. J. Cunningham of the Ontario Cancer Institute (OCI) in Toronto.

In 1972, AECL entered into an agreement with the OCI to develop and market a commercial treatment planning system (the TP-11), based upon Dr. Cunningham's research methods and using the PDP-11 computer. Numerous improvements have been made to the initial system, including the ability to input CT scan information directly to the computer. Theraplan, the current model of this system, was introduced in the early 1980's. Theratronics have marketed this product in the highly competitive field of information technology. Theraplan is sold in most parts of the world and is very popular in the USA. It is believed to be the only commercial treatment planning system currently in use in Canada.

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21 An oncologist would suggest that treatment planning encompasses many other factors, such as the previous medical history, age, and current health of the patient, consideration for the use of surgery or chemotherapy alone, with each other, or one or both combined with radiology, and the visual impression of possible orientations of the treatment machine(s), as provided by a teletherapy "simulator".

2.4 AUDITS AND RECALLS

One of the requirements of this study [Appendix I] is to respond to the following question:

> Q1. Do these case studies suggest a need for specific changes or improvements to the way the Environmental Health Directorate uses the HPB Risk Assessment/Risk Management framework in planning and conducting its operations? Are there factors that must be addressed which fall outside the HPB framework?

A review of the FOD actions and the BRMD findings regarding audits of Theratronics and the subsequent equipment recalls, is a necessary step towards making this determination.

In February 1992, armed with the newly introduced Regulatory Authority, Compliance Officers of the USFDA performed an unannounced audit of Theratronics USA Sales and Service offices in Carrollton, Texas. The USFDA had, at that time, received reports of failures in the Theratron 780 equipment, and the Therac 25 accidents were still newsworthy. They found sufficient product performance, record keeping, and reporting deficiencies that they requested a "voluntary recall" of products within the USA. They informed the FOD of their decision and offered to allow the FOD the opportunity to observe their audit of Theratronics Head Office and manufacturing facilities in Kanata. This audit was performed from April 27 to May 08, 1992 by three Officers of the USFDA, with two of the FOD present. As a result of this audit, Theratronics made a "voluntary stop shipment" to all its cobalt teletherapy and treatment planning products in Canada and other parts of the world. The FOD report of the USFDA audit was made on May 11, 1992 [Syzmanski (1992)]. The purpose of FOD's presence during the USFDA's audit of Theratronics was described in Syzmanski's report as follows [*emphasis added*]:

> "(1) To *observe FDA investigation proceedings* and gather information on how the firm handles complaints investigations and carries out corrective actions.
>
> (2) to *verify the firm's repeated violations* of the recall reporting requirements."

In other words, the FOD was "tagging along" while a foreign regulatory body was conducting an audit of a Canadian Company within Canada.

The FOD report listed four instances where safety related corrections or recalls had not been reported to the Health Protection Branch, in contravention of the Medical Devices Regulations. It also listed, 14 additional items where Theratronics was in violation of the regulations. The report concluded with a damning summary of Theratronics actions and of the safety of most of their products. This summary included a conclusion that by "[N]ot notifying users of the potential problems with the devices indicates that Theratronics *knowingly exposes the public to an unreasonable risk of substantial harm.*". [*emphasis added*].

When Theratronics was unable to arrange a speedy resolution of the situation, the BRMD was brought in to provide "expert advice" to the FOD on ways that the purported problems could be corrected. All officers of the BRMD who were interviewed expressed regret that, prior to consulting the BRMD, the FOD had placed Theratronics in a position where it felt compelled to issue a "stop shipment" order.

An investigation of the points raised in the FOD report [Syzmanski (1992)] was prepared by BRMD and issued in August 1992 [Symonds (1992a)]. This latter report used, as an evaluative framework, the HPB risk assessment/risk management model [HPB (1990)] and, from an analysis of problem reports and other Theratronics documents, stated the following:

- The investigation confirmed that, based on current HPB and manufacturer's problem reports, no potential safety hazards have been overlooked.
- For the majority of potential problems identified, the manufacturer has carried the health risk determination process through to the *implementation* phase.
- Due to the intuitive nature of the [Health Protection] Branch *Health Risk Determination* model, the manufacturer has followed approximately the same process as the Branch would have used in the same situation.
- With regard to cobalt teletherapy equipment, potential radiation safety hazards involving source and collimator positioning failures were identified. These could result in unwanted dose to the operator or maintenance staff or improper treatment dose distribution to the patient.
- The dual timer unit [of the cobalt teletherapy equipment] was evaluated and no safety related problems could be identified. The test protocol developed by Theratronics in 1983 was adequately developed and maintained and meets the criteria for "good current practice".

- This investigation [of treatment planning systems] classified fifteen current problems as being not safety related and sixteen as having the potential to influence treatment plans in a significant manner.
- With regard to the adequacy of testing of the [treatment planning] system, the pre-1990 development was found to conform to the concept of "good current practice".

In other words, the report found that Theratronics had developed these products in a manner commensurate with the standards of the day.

Despite the generally positive tone of this report, and vigorous actions taken by Theratronics to meet the requirements of the USFDA (and hence the FOD), it was almost two years before Theratronics was permitted to ship these products again.

Although the AECB has considerable Regulatory Authority under the *Atomic Energy Control Act*, it was only advised subsequent to the audit and recall actions. The Board took no actions in this case, because the safety-related items appeared to concern only the patient, and these the Board considers to be outside its jurisdiction.

3. DISCUSSION

There are three main areas of discussion arising from the events and actions described in Chapter 2 that need to be explored in the light of the evaluation questions we have been asked to address. These are: the relevance of the HPB risk assessment/risk management model as it applies to cobalt 60 teletherapy and treatment planning systems, the effectiveness of the communications activities of the BRMD with regard to these products, and an apparently significant gap in the jurisdictional responsibility for these products.

3.1 RISK ASSESSMENT AND RISK MANAGEMENT

We understand that HPB's risk assessment/risk management model, described in the document entitled *Risk Management in the Health Protection Branch* [HPB (1990)] applies to all Directorates of the Branch. In this study, we have been asked to comment on the model's relevance to the problems encountered with Theratronics cobalt 60 teletherapy equipment and treatment planning systems. We have chosen to consider the eight steps of the model as they apply to cobalt 60 teletherapy, and will look at treatment planning systems only where it differs from the teletherapy model. The eight steps are:

1) HAZARD IDENTIFICATION — The hazards due to high doses of ionizing radiation have been studied in detail and are well known and understood by the BRMD, the users of this equipment, and, to a sufficient extent, by the suppliers of equipment. Hazards associated with teletherapy equipment also include mechanical (crushing) and electrical (electrocution) in addition to radiation.

2) RISK ESTIMATION — We would argue that those who regulate the use of equipment should make a detailed analysis of the product risk prior to the equipment being marketed.[22] Such analysis should include estimates of risk from, software, mechanical and electrical hazards, as well as from ionizing radiation. It should also include risks to the general public, operating technicians, service personnel, and to the patient. Some knowledge of the medical aspects of the device is required if one is to understand how it is used and to estimate the magnitude of its claimed benefits. If the manufacturer has implemented a structured quality assurance program, this would assist the

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22 It was pointed out to us by a reviewer of the draft version of this report that: 1), a regulatory role before the equipment is sold implies "pre-market review"; 2), under Part V of the Medical Devices Regulations, premarket review is already based on risk estimation and is generally restricted to higher-risk implantable devices; and 3), should pre-market review be extended to such items as cobalt 60 teletherapy equipment there would be considerable implications (unstated) for the Department regarding resources, policy, and practicability.

regulators in their task of making an accurate estimate of the risks. This is especially true of equipment that utilizes software: while it may not be possible to make a precise evaluation of risk due to errors in software, a structured software design and testing program makes it possible to make a reasonable estimate. Unless such risk assessments are made by well-qualified personnel, subsequent decisions that result may not be in the best interests of public safety.

3, 4) DEVELOPMENT OF OPTIONS AND OPTION ANALYSIS — As was discussed in Chapter 2, cobalt 60 teletherapy equipment is regulated by the *Atomic Energy Control Act* and by the Medical Device Regulations of the *Food and Drugs Act*. While the *Radiation Emitting Devices Act* is written in such a manner that it could also be applied to cobalt teletherapy, it is apparently excluded by s. 3 of that Act (see discussion in Section 2.1). Treatment planning systems have recently been evaluated as though they were medical devices[23] [Symonds (1992b)].

Although it would appear that there are sufficient Regulations in place to meet all contingencies, this is not quite the case. To begin with, the authority with respect to regulation is too fragmented; the AECB, the FOD of the Health Protection Branch, various Provincial health and labour authorities and finally the BRMD of the Environmental Health Directorate, have all played a role in the regulation of cobalt 60 teletherapy equipment. It appears to us that no regulatory body has accepted full responsibility for the safety of the patient[24] and we shall discuss this further in Section 3.3.

5) DECISION — The model acknowledges that decisions regarding risk management may not always occur within the Health Protection Branch. Such a situation exists in the case of cobalt 60 teletherapy, where the AECB have assumed the responsibility for design approvals of the equipment and their safety with respect to the radiation exposure to the general public and operating personnel [AECB (1990)] — but not, as far as we can judge, to the patient. The area of physician responsibility for patient safety is, of course, also outside the jurisdiction of the HPB.

6) IMPLEMENTATION — The *Food and Drugs Act* and the Medical Device Regulations address clinical effectiveness and safety, and, as was pointed out to us, regulatory controls can be implemented if deemed appropriate. In addition, for many of the hazards managed by the HPB, an implementation strategy requires effective risk communication to the public. We do not feel that the

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23 An internal BRMD memorandum indicated that it was unclear whether treatment-planning systems were "medical devices" but, in taking a "prudent course of action", treated Theraplan as though it were a medical device [Symonds (1992b)].

24 An observation on this point was provided by a reviewer of the draft version of this report who stated:

"The treating physician is responsible for patient safety as part of the practice of medicine which is within provincial jurisdiction."

public (i.e.: the patients) need to be informed of risks due to failures of cobalt 60 teletherapy equipment. These are very ill people who have plenty to be concerned with in weighing the very real risks of treatment against the outcome of their illness — communication on such matters is most properly the responsibility of the attending physician. There are, however, a number of other important communication issues related to cobalt 60 teletherapy equipment and these will be discussed in Section 3.2.

7) MONITORING AND EVALUATION — The technique of post-market surveillance,[25] as listed in the risk assessment/risk management report, must be implemented to adequately ensure compliance of such relatively complex medical products as modern cobalt 60 teletherapy and treatment planning systems with the performance that is claimed for them — patient safety would be one aspect of this performance. We note, in passing, that these techniques must also be applied to various other products used in diagnostic and therapeutic radiology, such as electron accelerators, CT scanners, MR imaging systems, teletherapy simulators, and modern X-ray equipment. Medical equipment that is relatively complex is likely to be improved during its working lifetime and various components and sub-systems are likely to be changed, due to availability or new developments from the manufacturer's suppliers. Also, it is important that regulators have regular access to working experience with these equipment, either through the vendors problem reports or through the users and, preferably, both sources of information. This information will often point to areas of weakness in the equipment, such that appropriate actions can be taken to avoid health hazards resulting from malfunctions of the equipment.

   It is not clear that there are mechanisms in place for regular monitoring and evaluation of cobalt 60 teletherapy and treatment planning systems. This lack may, in part, be due the apparent fragmentation of regulatory authority.[26]

8) REVIEW — As mentioned in the model, review is a continuing process — enhanced products are introduced and new quality assurance standards are developed. As an example, when the Theratron 1000-C, a computer controlled cobalt teletherapy machine, is evaluated, this may suggest a review of the lessons learned by HPB with the Therac 25 accelerator, some of which may be applicable to cobalt equipment.

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25 It was pointed out to us (in January 1985), by a reviewer of the draft version of this report, that such post-market surveillance carries with it both regulatory implications for the Department and resource implications for the Bureau.

26 A reviewer of the draft version of this report provided the following explanation:

"The fact that there is no mandatory pre-market approval or post-market surveillance for teletherapy equipment has nothing to do with fragmentation of authority, but rather is due to the way the Department determined that medical devices should be regulated."

The above represents our interpretation of the risk assessment/risk management model as it may be applied in a general way to these equipments. We shall now examine each of the systems in greater detail.

3.1.1 Theratronics Cobalt 60 Teletherapy Equipment

To provide a perspective on the consequences of failures of cobalt 60 teletherapy equipment as identified in the audits, we attempted order-of-magnitude estimates of exposures to hospital staff and inappropriate radiation to patients as a result of these failures. The incidents and exposure consequences are summarised in Table 3-1 which, in turn, is based on the BRMD report [Symonds (1992a)].

As may be seen from the table, it is unlikely that any operator or technician would have received a radiation exposure in excess of 20 mrem, which is near the lower limit of accurate readings with thermoluminescent dosimetry (TLD) badges used to monitor such exposure and represents only a fraction of a percent (0.4%) of the maximum allowable annual exposure for atomic radiation workers. In a like manner, it is highly unlikely that any patient would have received an overexposure exceeding five percent of the tumour dose, a figure generally accepted as being the minimum that has clinical significance. In the case of the collimator drive positioning failure, however, some healthy tissue may have been inadvertently irradiated (although it would have been subject to some scattered radiation, in any event).

In contrast to these inadvertent exposures, are the benefits resulting from the use of this equipment. Assuming that each machine gives 100 treatments per week, 50 weeks per year, and that the average number of fractionated treatments per patient is 20, then 250 patients are given a course of treatment each year. Assuming that a cure rate of 25 to 30 percent results from these treatments, there will be a saving of 60 to 75 lives wholly or partially due to the use of each cobalt 60 teletherapy machine each year. As there are about 50 Theratronics cobalt 60 machines currently in operation within Canada, the net saving is of the order of 3,000 to 4,000 lives per year. While we stress that these figures should only be taken as a rough guide, it is seen that preventing even one treatment centre access to a teletherapy machine for any extended period could have potentially serious medical consequences.

TABLE 3-1 *Summary of Incidents Involving ^{60}Co-Teletherapy Machines Manufactured by Theratronics*[27]

TYPE OF INCIDENT	IMPLICATIONS
Rapid air loss: source failed to return to shielded position.	One incident in Canada. Reasonable to expect patient to be removed in less than 60 seconds. Overdose to patient — not more than 100 rads, or 2.5 % of total dose (Symond's report estimated 1 % as typical). Unless this was the final of 20-30 treatments, overdose can be corrected in future treatments. Dose to treatment technician removing patient — probably 10-20 mrem, less than 0.4 % of allowable maximum annual dose. Dose to service technician returning source to shielded position — probably 10-20 mrem, less than 0.4 % of allowable maximum annual dose.
"Single point" electronic failures: similar result to rapid air loss.	Four or five such failures. No known incidents in Canada.
Collimator drive positioning failure: collimator drive unable to hold collimator block tray in correct position when Theratron 1000 used with the heavier beam-shaping blocks designed for accelerators.	This could be regarded as misuse by the treatment centre, rather than equipment failure. Incorrect orientation of radiation beam to patient. Part of tumour would not be radiated during treatment and part of healthy tissue would be exposed to 100 rads, say. Difficult to completely correct for error, which would likely be 2.5 % or less to a portion of the tumour dose.
Ceiling mounted hand control could loosen with use: control unit could fall	The unit is not very heavy and unlikely to cause more than a bruise if it should fall on operator.
Loosening of wedge screws: wedge filters could fall.	Technician should be able to see that these are working loose, but if wedge filter fell it could cause a bruise to the operating technician or patient, and possibly add to the trauma of an already very ill patient.
Dual treatment timer failures: inaccurate irradiation times.	The Symond's report analyzed seven types of failures of the dual treatment timer and concluded that no hazard existed. We do not have the time nor the resources to challenge this analysis, which appears complete and rational.

27 This summary was compiled from information provided in the report, *The Investigation of Safety Related Problems with Radiation Therapy Equipment Manufactured by Theratronics International Limited* [Symonds (1992)]. We did not undertake an independent investigation of the events.

As was noted in Section 2.4, it took almost two years of concentrated effort by Theratronics before the "stop shipment" order was lifted. During that period, at least one hospital in Vancouver had to transfer patients to the USA for treatment, when only the control console was lacking on its equipment. Given the discussion above, the benefits from the use of these equipments clearly outweighs the minimal risks posed their deficiencies.

The decisions that led to the "stop shipment" order took place in the aftermath of a series of equipment failures involving the Therac 25 (a medical electron accelerator) that resulted in fatalities. To add further perspective to this discussion of risks involving cobalt 60 teletherapy, we therefore feel that a comparison of the potential hazards of cobalt 60 machines and medical accelerators is order.

The most powerful cobalt machines will deliver a radiation beam of perhaps 200 rads per minute. This results from the output from the cobalt 60 source, which is essentially constant. Those accelerators that operate in both electron and X-ray treatment modes, such as the Therac 25, have the potential for exposure rates at least 1,000 times this value [Symonds (1993), Leveson and Turner (1993)], should the equipment fail in the worst possible scenario, which is what actually transpired in the Therac 25 incidents. Although the different tissues of the body have varying degrees of sensitivity to radiation, most organs of the body will be unlikely to recover if exposed to a single dose of 8,000 rads and, if this is a critical organ, the irradiation will be lethal [Leveson and Turner (1993)]. Thus, while an accelerator has the potential to deliver a lethal dose in less than five seconds, this would require an operator to be inattentive for nearly an hour with a cobalt 60 machine. Clearly, therefore, any malfunctions in cobalt 60 teletherapy will be of a less "acute" nature.

3.1.2 Treatment Planning (Theraplan)

It must be stressed that a treatment planning system is an adjunct to the treatment process: it does not perform diagnosis or deliver any radiation to the patient. It is a sophisticated computational tool that provides information to assist medical staff to develop the optimal treatment protocol for each patient. A treatment planning system is not a substitute for medical judgement: indeed sound medical judgement is required to take advantage of its capabilities. Theratronics is well aware of the limitations of

Theraplan in this respect and include a warning in the Theraplan operators' manual. The warning, in part, states: "The software described herein is intended for a trained and qualified Medical Physicist, for interpretation by a Radiotherapist. Use of this software for the production of patient plans by untrained individuals is dangerous" (information extracted from Symonds [1992a]). Treatment plans reviewed by competent professionals are immune to catastrophic failure. If computations result in errors of less than 5 %, there will be no discernible clinical effects. One must remember that there are inaccuracies in all methods of treatment planning, as well as in all stages of the treatment process. It is only those software system faults of clinical significance that may escape the eye of trained medical specialists that should be regarded as "failures". It has been estimated [Symonds (1992a)] that these medical personnel should be able to detect all inaccuracies greater than 15 percent and perhaps as low as 10 percent.

The BRMD Report [Symonds, 1992a] discussed sixteen Theraplan problem reports that could result in a positional or dose estimate error that could be significant. A summary of these deficiencies, their implications, and the Theratronics corrective actions, as assessed by the BRMD, is given in Table 3-2. The table does not include product deficiencies which could result in obvious errors, very-small or zero-dose error, very small positional error, or deficiencies that do not produce any hazards. It should also be noted that Theratronics took prompt action to advise all users and to correct these problems as soon as they became aware of them. The FOD [Syzmanski (1992)], in its comments on the array-processor problem (third item, Table 3-2) commented, in a highlighted statement, that "[T]his recall has not been reported to the HPB".

The problem to which this statement refers was discovered by Theratronics in their own laboratory in April 1991 and the only system located in Canada affected by this deficiency was corrected within three weeks [Syzmanski (1992)]. At that time, there was (as we have previously discussed) no consensus that treatment planning systems were to be regarded as medical devices. Under these circumstances, it is reasonable that Theratronics would not feel obliged to report these or other deficiencies in Theraplan to the HPB.

A BRMD report [Symonds (1993b)] found that Theratronics, at all times, used programming techniques and software quality standards which were in line with current

TABLE 3-2 *Summary of Problem Reports Concerning the Theratronics Theraplan Treatment Planning System* [28]

PRODUCT DEFICIENCY	IMPLICATIONS	CORRECTIVE ACTION
Software performed incorrect collimation rotation simulation with "Beams Eye View" function	Incorrect treatment volume identified (possible. Dose errors.	Software update
Error in "software shuffle" routine	Incorrectly assigns target density, resulting in dose error.	Software update
Fault in an array-processor memory board, made by a third-party	Could *possibly* cause a non-obvious dose error.	New boards provided by Theratronics
In multi-workstation environment, planning moves from one workstation to another	Recalculation without changing treatment unit file would cause errors.	User advisory
Incorrect use of wedge tilt	User error.	User advisory
Various minor software deficiencies (5 problems)	Dose error <5%.	User advisory
For negative TAR/TPR values at surface, the plan may not be corrected	Dose error, difficult to estimate.	Users advised to use an array processor
Incorrect positioning of wires, using the "3 FILM" technique	May be limitation of algorithm. No estimate of dose error.	User advisory
Creative operator could cause errors with digitizer in non-CT contouring	Could result in large dosimetry error.	User advisory
Possible to improperly use "BEST FIT PLANE" program for seeds	Could cause dose error.	User advisory
Patients moved between workstations, then editing contours could cause offset	Up to 10% potential error.	User advisory
Adding seeds after origin shift causes new sources to collapse and, in effect, disappear	Theraplan is used as a dosimetry tool here, could cause dose measurement error.	User advisory

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28 This summary was compiled from information provided in the report, *The Investigation of Safety Related Problems with Radiation Therapy Equipment Manufactured by Theratronics International Limited* [Symonds (1992)]. The problems presented in the table are those that Symonds defined as potentially "significant". We did not undertake an independent investigation of the events.

industry standards. These standards were not sufficient to meet the requirements of the USFDA or the FOD, however, and Theratronics undertook a major "Revalidation Project" for the TP-11 and Theraplan software [Symonds (1993b)]. This included ten major quality assurance verification stages, based primarily on IEC Standards [IEC (1990)]. The "stop shipment" order on Theraplan was not lifted until some months after the BRMD report in 1993, which concluded that Theratronics had met the newly-imposed rigid quality assurance standards for a treatment planning system. During much of this period at least one treatment centre in Winnipeg was denied access to the Theraplan system it wished to purchase and place into service.

3.1.3 Approaches to Regulatory Control

Regulatory control is one means by which risk management may be implemented and it may be applied in a number of ways. The Canadian approach to regulatory control — which is cooperative and performance based — is, we would argue, preferable to the rigorously prescriptive approach taken by the USFDA. The USFDA system leads to a confrontational approach when problems arise, and results in a very onerous paperwork burden for both the regulatory authority and the vendor, without a clearly demonstrated enhanced safety payback. It has been stated by officers of the RPB that their role with regard to cobalt 60 teletherapy and treatment planning systems, because they act as advisors to other groups, is strictly reactive.[29] Although we accept this as being a statement of the facts, it is unfortunate because we feel it is necessary to take a proactive stance in order to apply the Health Protection Branch's risk assessment/risk management model to these classes of equipment. Only by following all technical aspects of a product (radiation, mechanical, electrical/electronic, software, etc.) during all phases of its life cycle (design/development, production, testing, in-field service) and considering all groups who may be exposed to hazards (the public, operating personnel, service personnel, and the patient) can a regulatory body truly discharge its duties in the most

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29 A clarification to this statement was provided by a reviewer of the draft version of this report who stated:

"[T]he reactive role is only in the context of the *Radiation Emitting Devices Act*. While the Department has the potential of assuming a proactive role under the *Food and Drugs Act* and the Medical Device Regulations by means of pre-market review and mandatory post-market surveillance, it has chosen not to do so. This policy is based on the risk model, with only those devices listed in Part V of the Medical Device Regulations being deemed of high enough risk to warrant pre-market review."

efficient and effective manner.[30] Many of the technical aspects of the product are interrelated, problems that result in hazards may appear during any phase of the product life cycle, these phases are also interrelated to some extent, and hazards cannot be neatly compartmentalized into classes of persons being affected. For example, the problems on the Theratron cobalt units addressed in this study had exposure implications for operating personnel, service technicians and patients.

3.2 COMMUNICATIONS

One of the objectives of this study is to evaluate the communications activities of the BRMD with regard to cobalt 60 teletherapy equipment and treatment planning systems. A major function of the BRMD was to act in these matters as, in the words of one of those interviewed, an "information broker". But to consider communication, which all interviewed acknowledged to be a "two way street", it is first necessary to define the clients of the BRMD. For the purposes of our study, these clients are the cancer-treatment centres and other government departments outside the EHD (specifically, the FOD and the AECB).

Let us first consider the community of treatment centres that use cobalt 60 teletherapy and treatment planning devices. This is the field of therapeutic radiology and the persons who have the responsibility for the safe operation and quality of performance of the equipment are the clinical medical physicists. As we have already mentioned, there are about 50 cobalt machines and 25 treatment planning systems in service in Canada.[31] The relatively small number of clinical medical physicists working in therapeutic radiology in Canada are in frequent contact with each other. Most of this communication is of an informal nature; they compare notes, and when one centre finds

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30 A reviewer of the draft version of this report offered the following comment on the practicability of our suggestion:

"From the safety point of view, it would indeed be ideal to have one group deal with all aspects — radiation, electrical, mechanical, chemical, ... — of the system. In real life, it is not practical unless there were a pool of experts from which groups could be assembled to meet the needs of the day. To follow the product from its inception through all phases of its life is just out of the question, given the number of models of radiation emitting devices coming on the market. It would also require a substantial change in the law."

31 Other radiation equipment that is in use in the same field includes perhaps 40 or 50 accelerators, ten or so teletherapy simulators, and possibly one or two brachytherapy units.

problems or peculiarities with a particular model of equipment it is soon common knowledge among all those who use that equipment. In situations where clinical medical physicists feel that others may make a contribution towards solving their technical problems, certain respected professionals are asked for help and within this latter group are some members of the RPB, a few at the AECB and (perhaps) one or two physicists at Theratronics. Together, these groups form a "grapevine" for information. This informal information-exchange mechanism, we were told, works very well and it is much to the credit of the RPB that some of its officers have such ready access to this timely source of information. The RPB (as did the BRMD), acting as an "information broker", refers the users to the appropriate provincial authorities or, if the problem is one of equipment design, contact the manufacturer to ensure that the problem is resolved.

The BRMD provided an analysis of the situation that led to the voluntary stop shipment shortly after it was requested by the Field Operations Directorate. The information provided to the FOD was well presented and, in our opinion, was of a high quality. Indeed, in the two formal reports [Symonds (1992b, 1993b)], the author demonstrated competence in a remarkable number of fields: the physical behaviour of radiation, software, quality assurance standards, as well as an informed understanding of the radiotherapy treatment process.

As we have noted, communications is a "two-way street" — the FOD took precipitate action before it consulted the BRMD, and once embarked on a given course, it became very difficult to reverse direction. The FOD's action, which resulted in the "voluntary" stop shipment of Theratronics equipment, appears to have been based on the rigorous prescriptive standards used by the USFDA, rather than the performance based standards normally applied in Canada. The BRMD was then requested by the FOD to specify the conditions under which Theratronics would be allowed to resume shipments. This request put BRMD in an awkward position because, as we have discussed above (Sections 2.4 and 3.1) there was a feeling within the group that there had not been adequate analysis by FOD prior to the stop-shipment action. Under these circumstances, one is tempted to ask whether the result would have been different if the BRMD had been made aware (in a "timely" fashion) of FOD's intentions before the stop-shipment order was issued.

3.3 RESPONSIBILITY FOR THE PATIENT

The health of the patient, as was pointed out in Section 2.1, is of course the responsibility of the attending physician (radiotherapist in this case) and her/his supporting staff. We would presume, however, that their responsibilities in this respect would end with reasonable care of the equipment and the proper use of it as a medical device. In the course of our interviews, however, we became aware of an apparent gap in regulatory authority for cobalt 60 teletherapy equipment.

It appears that no federal-government agency has accepted responsibility for the safety of the patient in the event of malfunction of cobalt 60 teletherapy equipment. The AECB is responsible for the safe operation of the facility, but claims that it has no responsibility for the safety of patients undergoing treatment. Patient safety could be considered to be covered tangentially in the *Radiation Emitting Devices Act*,[32] but cobalt 60 teletherapy seems to be specifically excluded from the RED Act (see discussion in Section 2.1). The *Food and Drugs Act*, which "imposes restrictions on the manufacture, sale and advertising of ... therapeutic devices to ensure safety and prevent deception" [HPB (1990), p. 136], obviously can be applied using the Medical Device Regulations of the Act. It would seem, however, that there is no provision within the Regulations for inspectors to enter the treatment centres where the equipment is being operated,[33] nor is there any requirement for the manufacturer to disclose failures of the equipment unless such failures result in a recall or corrective action (s. 29 to 31 of the Regulations). Consequently, any actions taken by Health Canada respecting the Medical Devices Regulations will only be taken <u>after</u> there has been unwanted radiation exposure to the patient and then <u>only</u> if the manufacturer deems it necessary to issue a "recall" or

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32 The Act has provision for developing regulations "for the purpose of protecting persons against genetic or personal injury, impairment of health or death from radiation" that can prescribe "standards regulating the design, construction and functioning ... of radiation emi'ting devices" and deal with the "labelling, packaging and advertising of radiation emitting devices" [s. 13(1)b and s. 13(1)d of the Act]. And, we would assume, "protecting persons" includes the protection of patients (i.e., patient safety).

33 A reviewer of the draft version of this report provided clarification on this point:

"The *Food and Drugs Act* and the Medical Devices Regulations cover the <u>sale</u> of medical devices. Hence, there cannot be regulatory authority for inspectors to enter treatment centres where the equipment is being <u>used</u>."

"correction". This, admittedly harsh, conclusion is mitigated somewhat by the informal information exchange that occurs within the health-care community; an exchange which, as described in Section 3.2, RPB is (and the BRMD was) part. Thus there is a mechanism, albeit an informal one, by which Health Canada could become aware of problems and, should it be considered necessary, institute some form of corrective action.

The uncertainty regarding regulatory responsibility for the patient undergoing radiation-teletherapy treatment is not a new phenomenon. Symonds [1986], in an internal memorandum eight years ago, dealt with this question in regard to medical electron accelerators. In this memorandum, he considered two entities that have some responsibility for these machines, the AECB and the Provinces, and determined that "... neither agency assumes responsibility for the safety of the patient" and concluded that "this problem has been around for 15 years and must be resolved for once and for all".

With regard to cobalt 60 teletherapy equipment, we note that failures involving Theratron machines that resulted in the "stop shipment" actions in 1992, summarised in Table 3.1, caused some patients to be inadvertently exposed or improperly exposed to radiation. This was also the case with the failures identified in 1980-1981 with AECL cobalt 60 equipment, some ten years earlier, when failures of the cord reel and single digital timer resulted in relatively small overexposures [Gundaker (1980), Mahmud (1980), Dvorak (1981)]. Thus, there have been several failures of cobalt 60 teletherapy equipment during a period of more than a decade that have resulted in (albeit minor) unintended exposures to patients. This would appear to be sufficient cause to seek a solution to the regulatory problem of the lack of jurisdictional responsibility for the safety of the patient.

4. CONCLUSIONS AND RECOMMENDATIONS

This project has focussed on problems concerning cobalt 60 teletherapy equipment and treatment planning systems and the activities of the BRMD in response to them. It was complicated by confusion, at least on our part, over regulatory responsibility, both within the HPB and between Health Canada and other regulatory agencies.

During the interviews of BRMD personnel, we were informed that the primary role of the Bureau, with respect to these products, was to act as advisors to other groups, not only within the HPB, but also to other agencies, including cancer treatment centres. However, the BRMD has, at times, taken a more proactive role in the risk management of these products, particularly with regard to quality-assurance standards for software.

4.1 A GAP IN REGULATORY RESPONSIBILITY?

The primary aim of any regulations governing equipment used for medical purposes is surely the wellbeing of the patient. Two Acts — the *Radiation Emitting Devices Act* and the *Food and Drugs Act* (specifically, the Medical Devices Regulations) — are the responsibility of Health Canada. Both Acts provide similar powers of inspection and enforcement, and it would appear that either could be used to regulate the use of teletherapy products. As mentioned in Section 2.1, however, it appears that cobalt 60 teletherapy equipment is excluded from the *Radiation Emitting Devices Act* and there is some doubt that treatment planning systems qualify as "medical devices".[34] On the other hand, there is agreement that cobalt 60 teletherapy falls within the Medical Devices Regulations of the *Food and Drugs Act*. These regulations seem to provide an adequate vehicle for action in the interests of patients.

Despite the apparent adequacy of these regulations, it does not appear that monitoring of cobalt 60 equipment problems has been undertaken on an on-going basis by HPB. On three separate occasions (in 1980/81, 1985/86, and 1992), failures of

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34 This point was clarified by a reviewer of the draft version of this report, who commented:

"An opinion has been expressed by Legislative and Regulatory Process [of Health Canada] the treatment planning systems are medical devices."

AECL/Theratronics equipment resulted in unwanted radiation to patients. On each occasion, corrective action was only taken by HPB as a result of actions by the USFDA. The RPB/BRMD was called in after the events to act as advisors to rectify the situation.

The other federal agency with regulatory authority for cobalt 60 equipment is the AECB. This agency completes a review of equipment prior to its being placed into service and monitors the equipment and the facility in which it is housed, on a relatively regular basis. The AECB assessments are, however, limited to those aspects of the equipment that protect the operators and the general public outside the treatment facility. As was made clear to us in the interviews, the AECB is not concerned with equipment failures that could result in unwanted radiation exposure to the patient.[35]

In view of the activity in the early 1980s concerning problems with cobalt 60 teletherapy equipment, in which both RPB and BMD were involved, we find it surprising that no mention of these events were made in the previous program evaluation conducted in 1984 [PARD (1984)]. Indeed, this evaluation made no mention of EHD's activities in regard to radiation therapy in general. It is well beyond our mandate to investigate the rationalia behind the previous program evaluation, but it has been well documented that a series of very serious accidents involving Theratronics medical accelerators [Symonds (1992a); Leveson and Turner (1993)][36] occurred not much more than a year after that evaluation was completed. The subsequent, USFDA inspired, "voluntary stop shipment" action in 1992, covering both cobalt 60 equipment and treatment planning systems, indicates that the patient-safety issue has still not been resolved.

We are unaware of any on-going effort within the federal government to regularly monitor the record of cobalt 60 teletherapy equipment and treatment planning systems *vis-à-vis* patient safety. This state of affairs gives the appearance of a significant "gap" in regulatory responsibility.

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35 This particular situation may be changing. A reviewer of the draft version of this report offered the following information:

"Recently, the AECB has written to the provinces and health physics professionals suggesting that the Board become involved in patient safety. The proposal involves federally mandated quality assurance procedures for patient safety."

36 The events even made it into the popular press (see Rose [1994]).

Accordingly, we recommend that the EHD explore, in concert with other regulatory entities (both within Health Canada and outside), the possibilities of providing more regulatory attention to the safety of the patient undergoing radiation therapy treatment.

The objective of such discussions should be to develop a proactive approach, such that unwanted exposures to the patient resulting from equipment malfunctions are prevented, rather than after-the-fact corrections being implemented.[37]

4.2 THE HPB RISK ASSESSMENT/RISK MANAGEMENT MODEL

The HPB has a management tool in place — its risk assessment/risk management model — that, in conjunction with its regulatory mandates, provides a vehicle for on-going monitoring of cobalt 60 teletherapy and treatment planning systems. The model (discussed in Section 3.1) serves as the frame work for monitoring a product from its inception to its withdrawal from service (i.e., the product life cycle). The benefits of the product compared with its risks would be evaluated as part of the model's risk assessment stage, prior to allowing sale of the product. Continued monitoring of the product would be conducted to evaluate both its performance in service and subsequent modifications made to the equipment (i.e., the risk management of the model). This type of proactive approach parallels the quality assurance standards that a responsible manufacturer would apply during all phases of a product's life cycle

The model also can provide guidance with regard to events, such as those that lead to the voluntary "stop shipment" actions on cobalt 60 teletherapy and treatment planning systems in 1992. As we have argued in Sections 3.1.1 and 3.1.2, had the risk analysis stage of the model been applied prior to actions being taken, it is possible that less drastic action would have been taken. Instead, the BRMD was requested to evaluate the situation after the "stop shipment" order was in place.

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37 A reviewer of the draft version of this report made the following response to this recommendation:

"The recommendation here has enormous implications for medical device resources. Pre-market review is not required for these devices, and mandatory problem reporting is not required for any device. The expansion of the former, and the implementation of the latter would require a change in Departmental policy. The relative risk of radiation therapy equipment malfunction or failure, based on problem reports and when viewed in the context of all medical devices (such as anaesthetic equipment) is not large. To change the current Departmental policy of restricted pre-market review and voluntary problem reporting would require major resourcing decisions."

We would encourage EHD to make <u>full</u> use of the HPB risk assessment/risk management model in the management of risks associated with cobalt 60 teletherapy and treatment planning systems.

The model encourages a proactive approach, one that enables problems to be resolved before crises arise and drastic actions are required. If such an approach were adopted, Health Canada would be placed in a strong position when the safety of such equipment is brought into question by other agencies.

4.3 QUALITY AND TIMELINESS OF BRMD ADVICE

We were asked to comment on the timelines and quality of the information regarding cobalt 60 teletherapy equipment and treatment planning systems provided by the EHD [Q7a (a) &(b) in Appendix I]. A principal function of the BRMD was to provide expert advice to its clients. These clients included the FOD, the AECB and, in a more informal manner, the cancer therapy treatment centres. Having reviewed the formal reports and other communications that passed between the BRMD and the FOD related to malfunctions in Theratronics cobalt 60 teletherapy equipment and treatment planning systems, we conclude that:

The BRMD communicated promptly to the FOD when their advice was requested, and their technical reports were of a high quality, demonstrating an in-depth knowledge of the equipment and the requirements of the treatment centres.

We were also asked to consider where the clients would go for advice, if it were not provided by the EHD [Q7a (c)]. Given the actions of the FOD in respect to the incidents that resulted in the "voluntary stop shipment", one could argue that the answer to this question, at least in part, has been demonstrated by the fact that the FOD chose to follow the advice of the USFDA and to take action, prior to consulting the BRMD. We consider that this did not result in the most appropriate resolution of the situation.

4.4 AN IDEAL ORGANIZATION?

The recent reorganization that has occurred within the HPB — the redistribution of the, now disbanded, Field Operations Directorate functions within the Branch, the re-establishment of the Radiation Protection Bureau and the Bureau of Medical Devices as separate entities — presents an excellent opportunity to consider changes with a view of providing the most effective use of limited manpower resources. In light of our findings

and discussion we thought it would be appropriate to describe an "ideal" organization for the handling of radiation teletherapy and treatment planning systems. Not, we hasten to add, as a recommendation to be considered as a model for the newly separated RPB and BMD — their mandates are much wider than merely dealing with radiation teletherapy and treatment planning systems — but rather, in conclusion, to serve as a synthesis of the ideas discussed in this report.

Many of the radiotherapy products (both diagnostic and teletherapy) that fall within the EHD's jurisdiction are relatively complex. To be able to effectively monitor their use requires a knowledge of radiation, mechanical and electronic hardware, software, and the clinical application of the equipment. This knowledge is essential if the proper regulatory decisions are to be made on a consistent basis. As discussed in the section above, the HPB risk assessment/risk management model provides a convenient management tool that may be applied in the regulatory monitoring of these products. Such monitoring requires a continuum of expertise within the regulatory authority from product inception until the end of the product's useful life.

Accordingly, we would consider that an ideal organizational structure would be based on rather narrow "product expertise" lines. In other words, one could envisage there being a series of "groups" within the EHD and that each "group" would have an in-depth knowledge of all technical aspects of the products for which it would be responsible and of the products' clinical use.[38] Further, it would be incumbent on the "group" to consider all aspects of each product during that product's entire life cycle.

Such an organization, coupled with stricter adherence to HPB's risk assessment/risk management model may result in timely expert advice being applied more consistently. All of these actions will have a positive impact on the safety of the patient.

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38 In many ways, this type of organizational structure is complementary to the matrix-project system on which the activities of the EHD are conducted.

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APPENDIX I: SCOPE OF THE THERATRONICS CASE STUDY

The purpose of the study is to evaluate:

> The investigation of problems with Theratronics Co-60 radiation-therapy equipment and treatment planning systems conducted by the Bureau of Radiation and Medical Devices.
>
> In addition to the evaluation questions identified below, this case study shall also report the contractor's conclusions on the following evaluation question: "Q2. Are there things Environmental Health Directorate (EHD) should do to help improve the availability of, EHD access to, or the quality of information on a) the toxicity of and b) on actual or potential exposure to environmental hazards assessed under the Radiation Emitting Devices Act?"
>
> The case study shall also include an estimation of the number of persons potentially exposed each year to health risks from the Theratronics products, the level of health risk, the severity of that risk, and the effectiveness of the program's activities in this area.

and to answer the following questions on "the actions taken and advice given by the Environmental Health Directorate" with regards to problems experienced with Theratronics Co-60 radiation-therapy equipment and treatment planning systems:

(1) Q7a. EHD provides information and advice to governments, departments, agencies, and others to help them manage the health risks from environmental sources:

   (a) Do client decision makers get timely and needed information from EHD on health risks from environmental sources?

   (b) Does EHD provide the information in a useful format?

   (c) If EHD didn't provide this information and advice, where would these clients turn for information and advice? What would be the consequences if this were to happen?

(2) Q6. How effectively does the program communicate with specific interest groups and with the public about actual public exposure to radiation and chemical hazards, and known health risks from such exposure?

(3) Q1. Do these case studies suggest a need for specific changes or improvements to the way the Environmental Health Directorate uses the HPB Risk Assessment/Risk Management framework in planning and conducting its operations? Are there factors that must be addressed which fall outside of the HPB framework?

It was, however, beyond the mandate of this study to make contact with individuals and organizations that were outside the federal government. (Such contacts are to form another part of the program evaluation.) For the purposes of this project, the "client" referred to above constitutes other federal government departments (notably, the Atomic Energy Control Board) and cancer treatment centres.

APPENDIX II: BIBLIOGRAPHY PERTINENT TO THE THERATRONICS CASE-STUDY

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APPENDIX III: SUMMARY OF INTERVIEW TOPICS AND THE RESPONSES[39]

Interviewees: Three individuals from Health Canada
Two individuals from the Atomic Energy Control Board:

ORGANISATIONAL "STRUCTURE" AND HISTORY

Bureau of Radiation and Medical Devices

- Prior to 1986, the Radiation Protection Bureau (RPB) and the Bureau of Medical Devices (BMD) existed as two separate entities. These bureaus were amalgamated to form a single entity, the Bureau of Radiation and Medical Devices (BRMD). In September 1993, however, two separate Bureaus (RPB and BMD) were re-established.

- Prior to 1986, BMD kept strictly to the Medical Devices Regulations of the *Food and Drugs Act*, and passed on items involving radiation to the RPB. These demarcations ceased on amalgamation.

- Health and Welfare Canada had a Field Operations Directorate that conducted inspections under the *Food and Drugs Act*. Its operations were separate from the activities of the RPB, BMD and the BRMD. There was collaboration, especially regarding medical devices — problem reports, recalls.

The Field Operations Directorate

- Field Operations (which, on April 1 1994, ceased to exist as an independent Directorate) had no formal reporting relationship with the Environmental Health Directorate (rather, as do all directorates in the Health Protection Branch, Field Operations reported to the Assistant Deputy Minister).

- The Field Operations Directorate no longer exists as such, and its inspectorate functions regarding medical radiation devices will now be under the functional control of the Environmental Health Directorate.

- Traditionally, Field Operations had very little to do with medical devices of interest to RPB. This was because Field Operations did not have the expertise in radiation and, in addition, were "very thin on the ground" with regard to engineering expertise —

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39 By and large, each bullet corresponds to a response from an interviewee and thus there will be instances of repetition.

therefore RPB did most of the evaluations[40] of radiation-therapy units (and expect to continue to do so).

- Field Operations maintained a close relationship with the U.S. FDA — when the U.S. FDA said there was a "problem", Field Operations assumed that there was a "problem" also and acted accordingly.

  In both the dual-timer and the Theraplan/TP-11 cases, Field Operations took action because the U.S. FDA had taken action — RPB were then brought in after the fact to provide "expert advice" on appropriate actions to correct the purported problems.

- The Field Operations Directorate, at times, acted without the prior knowledge of the BRMD and only brought the BRMD in "after the fact".

  A particular illustration of this approach was the actions by Field Operations over the Theratron 780. The BRMD was brought in after these machines had undergone a voluntary recall at the request of Field Operations (an unwarranted action in the BRMD's opinion) to evaluate problems associated with the dual-digital timer and the treatment-planning system

- The actions against Theratronics with regard to Co-60 and treatment-planning systems were initiated by the former Field Operations Directorate without prior consultation with RPB

- With the reorganization, inspectors dealing with radiation-emitting devices and attendant accessories (e.g., Co-60 therapy equipment and treatment-planning systems) now come under the functional authority of the EHD — a great improvement.

- The reorganized inspectorate functions will avoid such conflicts in the future.

External Agencies (AECB, US FDA, and others)

- The AECB has nothing to do with treatment-planning systems.

- The AECB licenses the hospitals where Co-60 teletherapy machines are used[41] and has responsibility for the safety of staff operating the equipment.

- The AECB issues design approvals for teletherapy equipment, including Co-60 units. The Safety Review of these machines is strictly concerned with the safety, with respect to radiation exposure, of the public and operating personnel. The Safety Review includes assessment of head shielding, source on/off mechanisms, etc. in relation to such guidelines as IEC, ICRP, and ANSI standards. The AECB does not look at the mechanical- and electrical-safety aspects of the equipment, nor at those aspects related to the safety of patients.

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40 These were not done "in the field".

41 The AECB also used to license the physicians who carried out the treatment, but this responsibility is now shared with the provinces.

- The AECB also looks at the facility — e.g., interlocks, signage, restart protocols, bunker shielding, etc.

  The AECB inspects radiation-treatment facilities, on an average, about once a year — worker records, interlock checkouts, facility shielding, etc. — but does not specifically look at equipment functioning.

- Provinces have overall responsibility for worker safety at treatment facilities under provincial occupational health and safety acts (Ontario Ministry of Labour, for example, has a radiation safety group). Provinces also license operators. (Provincial radiation safety normally confines itself to non-AECB-licensed radiation material.)

- The BRMD has close links with the US FDA and relies on that Agency's occurrence reports, combined with other reports in the Medical Devices Registry database (now the responsibility of the Medical Devices Bureau), to identify problem areas with Co-60 teletherapy equipment and treatment-planning systems — it sees no point in "re-inventing the wheel" and maintaining its own list of occurrences. The BRMD also maintains close ties with the UK regulatory agencies (under a tripartite arrangement involving Canada, the US and the UK).

  The BRMD's US FDA links are really with the Center for Devices and Radiological Health[42] (CDRH, an organization that administers the US equivalent of Canada's *Radiation Emitting Devices Act*). In much the same manner as was the separation of responsibilities between Health and Welfare Canada's Bureau of Radiation and Medical Devices and its Field Operations Directorate, the US FDA maintains separate responsibilities for its CDRH and its compliance function.

STATUTORY CONSIDERATIONS

General Aspects

- *Radiation Emitting Devices Act* was promulgated *circa* 1970, while the Medical Devices Regulations under the *Food and Drugs Act* only came into being in 1978. However, the *Food and Drugs Act* itself (which covers the sale of unsafe devices), precedes the *Radiation Emitting Devices Act*.

- Stemming from the thrust of the *Radiation Emitting Devices Act* legislation, which essentially reactive in nature, RPB's approach to Co-60 and treatment planning also tends to be reactive (rather than proactive) — ∴ little or no on-going monitoring is carried out.

  The X-ray Section has an inspection unit that looks at these things

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[42] This agency used to be the Bureau of Radiological Health, with responsibility solely for matters concerning radiation and health, until it was expanded to include medical devices — in much the same manner as the amalgamation of the Radiation Protection and Medical Devices Bureaus in Canada.

- The *Radiation Emitting Devices Act* is strictly a "reactive" piece of legislation.

  There has never been any clear division of responsibilities as to who in Health Canada (the RPB or the Field Operations personnel) should be acting under the RED Act.

  There are inspectors appointed under the RED Act, and they report to the X-ray Section. But these inspectors cannot use their powers under the RED Act to initiate action concerning Co-60 machines — in the past, Field Operations or BMD would have to initiate action by requesting RPB to become involved.[43]

- The way the *Radiation Emitting Devices Act* has been written, however, means that Co-60 machines are not covered under that Act but, rather, are covered under the *Atomic Energy Control Act* which is administered by the Atomic Energy Control Board.

- Co-60 radiation therapy equipment are a "regulatory misfit". They do not fall under the *Radiation Emitting Devices Act*, being excluded by s. 3(a) of that Act, but under the *Atomic Energy Control Act*. There is tacit agreement, however, that RPB (rather than the AECB) deal with the medical aspects (AECB is responsible for the Co-60 source) — there does not appear to be a Memorandum of Understanding (MoU) between Health Canada and the AECB regarding this.

- There are "jurisdictional" problems regarding the ways that the Radiation Protection Bureau (RPB) can take action on Co-60 teletherapy machines.

  Co-60 machines are not entirely covered by any statute that Health Canada has jurisdiction over.

  RPB has no authority over the source (that is AECB's sole responsibility).

  With regard to the Medical Devices Regulations of the *Food and Drugs Act*, RPB originally acted as an "advisor" to the Bureau of Medical Devices (BMD) under a Memorandum of Understanding[44] — when the two Bureaus were combined, most of the "BMD" work was done by the X-ray Section. The Field Operations Directorate took action (often independently of RPB) under the Medical Devices Regulations.

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43 This has now changed. The RPB was given the responsibility to deal with all medical devices that emit radiation — this includes Co-60 teletherapy machines — under the *Food and Drugs Act*. In case of conflict with the *Atomic Energy Control Act*, however, the latter prevails.

44 This MoU between the two Bureaus agreed that RPB would handle all non-radiation aspects of the Co-60 machines and treatment planning systems — the MoU became redundant when the Bureaus merged. Now that Medical Devices has become separate again, another MoU is being considered.

> In the past, the only way the RPB would become involved with Co-60 therapy machines would be if there had been some sort of "accident" and they had been requested to do so by Field Operations or BMD.[45]

- Co-60 machines fall under the definition of "medical devices" and are therefore covered under the Medical Devices Regulations of the *Food and Drugs Act* — these regulations also deal with items ancillary to the device and this, by extension, can include treatment-planning systems.

- RPB, when it needs to, uses the Regulations under the *Foods and Drugs Act* that deal with medical devices and accessories (specifically, s. 19 and s. 20 of the Act) for taking action on Co-60 therapy equipment and on treatment planning systems.

- The Medical Devices Regulations (s. 14) contain requirements for "testing before sale" and it is these requirements that have been used by RPB in dealing with Co-60 therapy equipment and treatment-planning systems — eventually ISO 9000 will define the Good Manufacturing Practices that have to be used to satisfy requirements for "testing before sale".

- Good Manufacturing Practices (the underlying principle behind "pre-market review") is often not aimed at identifying hazards, and has not been applied to radiation-therapy equipment and treatment-planning systems.

- Pre-market review is not applicable to Co-60 therapy machines or treatment planning — pre-market review is normally carried out for those medical devices listed in Part V of the Medical Devices Regulations (implants, etc.). No RED Act devices are included.

- Under the present Medical Devices Regulations, treatment-planning systems, if they are in fact a "medical device," would not be subject to "pre-market review" because such systems are not items that are "implanted" into patients.

- RPB recognises that the regulatory activities of the provincial governments have increased in the past few years and will continue to do so. This does not require any new legislation on the part of the provinces, but is and will continue to be accomplished through their power-control Acts (e.g., the Power Corporation Act of Ontario). The requirements of these standards goes well beyond electrical safety, and into performance, software control, etc.

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The Situation with Regard to Patient Safety

- There are no specific regulations in Canada governing the safety of patients undergoing radiation therapy — patient safety is covered in a general way by parts of the *Radiation Emitting Devices Act* and the Medical Devices Regulations of the *Food and Drugs Act*. A number of jurisdictions in other countries, however, do have regulations covering patient safety — the U.S. Nuclear Regulatory Commission, for example, has regulations specific to the radiation dose received by the patient.

- The AECB does not consider it has responsibility for patient safety and cites the Schedule II exemption (which refers to radiation received by patients in the course of medical diagnosis or treatment) in the Atomic Energy Control Regulations as support for this stance.[46]

- The isotopes used in radiotherapy (e.g., Co-60) are outside the sphere of HPB's responsibilities, but everything else associated with radiotherapy is RPB's responsibility.

- Ontario has a Healing Arts Radiation Protection (HARP) Commission that was originally set up to look at X-ray safety, but it has recently expanded its mandate to included radiation-therapy treatment.

- There do not appear to be any Memoranda of Understanding between the AECB and Health Canada concerning patient safety and radiation therapy. (There was a tripartite meeting between AECB, RPB, and Ontario in the early 1970s that agreed on a 10 MeV energy "cut-off" for AECB's responsibility for medical linear accelerators.)

- Recently, the Canadian Association of Medical Radiation Technologists (CAMRT) dealt, in a newsletter article, with the roles and responsibilities of medical physicists in providing assurances that the radiation machines would deliver the dose prescribed by the physicians.

Thoughts on regulatory approaches

- In an "ideal" world, everything regarding "radiation beams" would be under "one roof".

- Arising from the publicity about the Therac 25 situation, the AECB questioned whether it might be held "responsible" for problems with therapy machines.

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46 Nonetheless, a report to AECB's Board of Directors reviewing regulations, in a number of jurisdictions throughout the world, regarding the safety of patients undergoing radiation therapy is being prepared by AECB.

- The AECB recognises its responsibility over radiation-treatment facilities and the safety of workers and the general public and would like to have some assurance that Health Canada was looking after patient safety (e.g., that the therapy machines were properly evaluated and monitored).

- The AECB would prefer standards that were performance based, rather than prescriptive (the U.S. FDA approach is rigorously prescriptive and this results in a very onerous paper-work burden.)

- In general, the present system in Canada — physicians, hospitals, and medical physicists, all in close communication about treatment protocols — may not be very tidy, but it works well.

RISK ASSESSMENT/RISK MANAGEMENT

The "Philosophy"

- Within the confines of the Regulations, the BRMD tends to look at the risk, evaluates it to determine if it warrants action and then, if necessary, acts — rather than taking an inflexible "rule book" approach.

- The common approach is to identify hazards and then proceed with actions that will manage the resulting risks.

- The RPB follows the Branch "philosophy" as outlined in the document, *Risk Management in the Health Protection Branch* (1990).

  Namely, hazard identification and risk assessment leading to assessment of "control" options — an approach that meets the intent of the *Health and Welfare Act* and the RED Act.

  This offers a greater degree of flexibility than a "command and control" approach.

- The RPB tries to resolve problems without having to resort to regulatory action. The RPB believes that this not only follows the Branch's philosophy on risk management but that it also achieves more with given resources than would a formal regulatory approach.

- The BRMD cannot duplicate the manpower and specific expertise that are available to manufacturers.

  The BRMD (from 1988 to present and the "new" Medical Devices Bureau) is in the process of developing a system for looking at theoretical risks and, using artificial intelligence approaches, predicting possible outcomes. (It may, however, take some time to get such a system accepted by professional staff, some of whom view such systems as an infringement on professional freedom.)

The Practice

- There are approximately 50 Co-60 radiation therapy machines and 25 Theraplan/TP-11 treatment-planning systems currently used in Canada.

- The RPB does not have a list of all the 50 or so Co-60 machines in Canada — such a list would have to be compiled from Co-60 source records held by AECB and from records of installations held by the Provinces.

  The compilation of such a list might be complicated by jurisdictional problems.

- Health Canada "registers" teletherapy units but, as far as the AECB is aware, does no follow-up inspections — AECB lawyers are of the opinion that if an agency takes a responsibility by registering equipment it is duty bound to ensure compliance.

- The choice of the RPB adopting a "proactive" rather than a "reactive" approach (or, indeed, vice versa) did not really apply to Co-60 teletherapy because RPB had to wait until it received a request from "others". (This was a case of close collaboration between RPB, and BMD and Field Operations.)

  To put this observation in the context of other activities within the X-ray Section:[47] The approach adopted with regard to X-ray equipment tends to be "proactive" despite the limitations of the reactive nature of the RED Act.

- The RPB has no mandatory reporting requirements and thus relies heavily on reports from manufacturers, users and the U.S. FDA — an organization that requires manufacturers to report problems arising from the use of their equipment anywhere in the world, if such equipment is used in the United States. RPB has developed an extremely close relationship with the U.S. FDA, but RPB's response is different — rather than relying on a rigid action protocol (as the U.S. FDA is required to do), RPB asks "is there a risk involved?" and then takes the action warranted. Prior to the splitting of the Radiation Protection and Medical Devices Bureaus (which occurred in fall 1993), RPB and BMD used the same surveillance unit to ensure that problem reports reached the right person. This function has remained with BMD, however, and RPB is investigating methodologies for accessing the problem-reports database in a routine and timely manner. This is a priority for the Transition to Functional Direction Team.

- There were no "events" with other manufacturers' Co-60 teletherapy machines that triggered the need for a response from RPB.

  RPB has no authority to "go on fishing expeditions".[48]

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47 Dealing with Co-60 therapy equipment and treatment-planning systems are only two of a number activities undertaken by the X-ray Section.

48 It should be remarked (with regard to reciprocity) that the U.S. FDA are willing to let authorities from outside the United States inspect manufacturers within that country.

- The RPB were never interested in treatment-planning systems until the U.S. FDA started raising questions some time around 1990 — the FDA action forced RPB to become active. The US FDA action was followed by Field Operations, who then requested expert assistance from the RPB. The RPB did not react directly to the FDA action.

  Part of the problem is that treatment-planning systems did not fit any definition of a "device" — neither a "medical device" nor a "radiation-emitting device" — ∴ such systems were not of interest from the regulatory point of view.

  The systems are not an accessory to any particular radiation machine — it is just a "tool" used by medical professionals to develop appropriate treatment regimes for individual patients. There is always a medical professional "standing between" this "tool" and the patient. Nevertheless it has been decided (eventually) to treat the systems as medical devices.

- It must be remembered that therapy equipment and the treatment-planning systems are used on people who are already very ill. With regard to patients, the major concern is dose delivery (±5% considered acceptable). Operator and technician safety are also of concern. In both these areas, RPB's job is mainly aimed at disaster prevention.

- Risk assessment can be a valuable tool for the setting of priorities to enable efficient use of available, but limited, resources.

COMMUNICATION

- Communication is very much a "two-way street".

The Health Canada Approach

- RPB acts, in many ways, as an information broker.

- Users contact RPB (both by telephone and in writing) with problems. If the problem concerns a treatment application, then RPB refers the user to the appropriate provincial authorities. If the problem is one of equipment or software design, RPB contacts the manufacturer and ensures that the problem is resolved.

- RPB does, from time to time, formally contact cancer-treatment centres — but, for most situations, it is not worth doing because the users already know of the problems. Hospitals, on their part, also contact RPB. In most instances, such communication is of an informal (verbal?) nature.

- For specific incidents, especially those of an "acute" nature, RPB commonly does a lot of work by telephone — this is often the most efficient way to get manufacturers to take corrective action. Written communications (letters and faxes) are also used.

- RPB uses the co-operation and assistance of operators of cancer treatment centres, professional organizations, trade associations, manufacturers, and other experts.

- RPB does communicate with manufacturers but, again, much of this communication is of an informal kind. An exception to this informal approach was, in the case of Co-60 therapy machines,[49] the instance of questions regarding good manufacturing practices concerning the Theratron 780 machine. In this instance, formal communication was handled by Field Operations (RPB, as mentioned above, provided Field Operations with expert advice) with RPB dealing directly with the manufacturer only in resolving technical questions.

- Manufacturers are very open and "up front" concerning problems with their products and with the resolution. RPB has a very good relationship with manufacturers.

- Although manufacturers generally behave as "good corporate citizens", there are occasions when manufacturers do not inform RPB of problems with their equipment. It should be noted, however, that if the problem arises from use or maintenance of the equipment, manufacturers do not have to report it to RPB. Reporting is only required if it is a problem of design, construction or functioning of the equipment.

The AECB Approach

- The AECB does communicates with RPB/BRMD as necessary. A meeting, for example, was held on 31 August 1994 to discuss jurisdictional issues. In 1991, AECB and BRMD discussed BRMD's development of Linear Accelerator Regulations, but this regulatory initiative was shelved.

- The AECB did have communication with Health & Welfare's Field Operations Directorate (Jim Moore and Penny Elwood) in 1991/92 over the U.S. FDA's audit of Theratronics. Subsequently, AECB began receiving regular occurrence reports from Field Operations (basically these were summaries of the U.S. FDA's occurrence reports).

- The AECB regularly receives the U.S. NRC publication, "Reports to Congress on Abnormal Occurrences".

- The U.S. FDA has an electronic bulletin board dealing with radiation therapy machines and the AECB regularly monitors it. The AECB, however, has no regular direct communication with the U.S. FDA.

- The AECB is in contact with Theratronics once every couple of months — mainly on transportation issues.

- In general, AECB relies on licensees and manufacturers for information — initial awareness of the Theratron 780 problems, for example, came via this route.

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[49] There are other instances where the RPB has adopted more formal approaches with manufacturers (e.g., the Therac 25 case, non-medical X-ray equipment), but these instances are outside the mandate of this case study.